UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

PAULINE and RICK MONCIBAIZ, Plaintiffs,	§	CIVIL ACTION NO. 4:20-cv-01315
vs.	§	JUDGE CHARLES ESKRIDGE
PFIZER INC, *et al*, Defendants.	§	

MEMORANDUM AND OPINION
GRANTING MOTION TO DISMISS

The motion by Defendants Pfizer, Inc, Wyeth LLC, and Wyeth Holdings, LLC to dismiss the claims brought by Plaintiffs Pauline and Rick Moncibaiz is granted. Dkt 12.

1. Background

This action relates to the manufacture and use of Prempro, a drug available by prescription to treat symptoms of menopause and to prevent osteoporosis in menopausal women. Dkt 12 at 11–12. Clinical studies have shown that some women who take Prempro experience an increased risk of breast cancer. Dkt 6 at ¶¶ 11–14.

A black-box warning appears with each prescription and explains this risk. That warning is approved for use by the United States Food and Drug Administration. See Dkt 12 at 10–13. It states in pertinent part:

> The estrogen-plus-progestin substudy of the Women's Health Initiative (WHI) reported increased risks of myocardial infarction, stroke, invasive breast cancer, pulmonary emboli, and deep vein thrombosis (DVT) in post-menopausal women (50 to 79 years of age) during 5.6 years of treatment with conjugated

> estrogens (CE 0.625 mg) combined with medroxyprogesterone acetate (MPA 2.5 mg) per day relative to placebo. (See **CLINICAL STUDIES** and **WARNINGS**, **Cardiovascular disorders** and **Malignant neo-plasms, Breast cancer**.)

Dkt 5-1 at 3 (emphasis in original). Other references to the risk of breast cancer appear in the *Warnings* section. Id at 24–28. The approved patient-information leaflet also contains a similar warning. Id at 41.

Pauline Moncibaiz took Prempro from 2008 to 2018, when she was diagnosed with breast cancer. She alleges that Prempro was the cause. She also alleges that she was unaware of several studies that discuss the risks associated with using Prempro, including the heightened risk of breast cancer. And she alleges that Defendants failed to inform her of safer alternative medicines. For example, she says, so-called bioidentical hormones have been shown to provide the same benefits as Prempro without involving the same risks. Dkt 6 at ¶¶ 11–17.

Together with her husband, Rick Moncibaiz, she filed suit against Pfizer and the Wyeth entities in the 189th Judicial District Court of Harris County in April 2020. Dkt 1-1. Defendants removed based on diversity jurisdiction. Dkt 1. Plaintiffs at that time asserted claims for strict liability based on allegation of design defect, breach of the implied warranty of merchantability, negligence, and gross negligence. This was done with reference to a failure-to-warn theory. See Dkt 1-1 at 1–2, 6. Defendants moved to dismiss, arguing (among other things) that the claims were all substantively based upon a failure to warn. Dkt 5. Plaintiffs sought and received leave to file an amended complaint to respond to those arguments. Dkts 7, 13.

Plaintiffs filed an amended complaint, reasserting claims for design defect, negligence, and breach of the implied warranty of merchantability. Dkt 6. Defendants filed the subject motion to dismiss. Dkt 12. They again argue that Plaintiffs' claims are in substance failure-to-warn claims—even though not formally pleaded as such—and thus subject to dismissal under Texas products-liability law. See Dkt 12 at 14–19. They argue further

that Plaintiffs fail to state a claim even if their claims aren't subject to dismissal as failure-to-warn claims. See id at 9–12.

2. Legal standard

Rule 8(a)(2) of the Federal Rules of Civil Procedure requires a plaintiff's complaint to provide "a short and plain statement of the claim showing that the pleader is entitled to relief." Rule 12(b)(6) allows the defendant to seek dismissal if the plaintiff fails "to state a claim upon which relief can be granted."

Read together, the Supreme Court has held that Rule 8 "does not require 'detailed factual allegations,' but it demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Ashcroft v Iqbal*, 556 US 662, 678 (2009), quoting *Bell Atlantic Corp v Twombly*, 550 US 544, 555 (2007). To survive a Rule 12(b)(6) motion to dismiss, the complaint "must provide the plaintiff's grounds for entitlement to relief—including factual allegations that when assumed to be true 'raise a right to relief above the speculative level.'" *Cuvillier v Taylor*, 503 F3d 397, 401 (5th Cir 2007), quoting *Twombly*, 550 US at 555.

A complaint must therefore contain enough facts to state a claim to relief that is plausible on its face. *Twombly*, 550 US at 570. A claim has *facial plausibility* "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 US at 678, citing *Twombly*, 550 US at 556. This standard on plausibility is "not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Iqbal*, 556 US at 678, quoting *Twombly*, 550 US at 556.

Review on motion to dismiss under Rule 12(b)(6) is constrained. The reviewing court must accept all well-pleaded facts as true and view them in the light most favorable to the plaintiff. *Walker*, 938 F3d at 735 (citations omitted). It must also accept all inferences that plausibly follow from those specific allegations. *Iqbal*, 556 US at 678, citing *Twombly*, 550 US at 556.

3. Analysis

It's undisputed that the FDA has approved warnings with respect to the prescription and dispensation of Prempro. It's also undisputed that these warnings came with the prescriptions for

Prempro used by Pauline Moncibaiz. See Dkt 18 at 9 (referencing "the FDA-approved warnings").

These facts are important because, since September 2003, Texas law has imposed a high burden for pleading failure-to-warn claims where the FDA has approved such warnings. See Reform of Certain Procedures and Remedies in Civil Actions, 78th Texas Legislature, 2003 Reg Sess (Sept 1, 2003). Texas Civil Practice and Remedies Code § 82.007(a)(1) now provides, "In a products liability action alleging that an injury was caused by a failure to provide adequate warnings or information with regard to a pharmaceutical product, there is a rebuttable presumption that the defendant or defendants, including a health care provider, manufacturer, distributor, and prescriber, are not liable with respect to the allegations involving failure to provide adequate warnings or information" if the warnings on the drug given match those approved by the FDA.

Texas law further provides only five ways to rebut this presumption. These are very specific. See Tex Civ Prac & Rem Code § 82.007(b)(1)–(5); see also *Johnson v Novartis Pharmaceuticals Corp*, --- F Appx ---, 2021 WL 406098, *3–4 (5th Cir) (citations omitted). The first is where the defendant withheld information from the FDA or made misrepresentations to it before premarket approval. The second is where the product used by the plaintiff was purchased after an order by the FDA requiring the defendant to remove the product from the market. The third is where the product was advertised for an indication not approved by the FDA, and the plaintiff's injury was caused by the improper advertisement. The fourth is where the product was prescribed for an indication not approved by the FDA, and the plaintiff's injury was caused by the improper prescription. The fifth is where the warnings approved by the FDA were approved in violation of 18 USC § 201, which prohibits bribery of public officials and witnesses.

Plaintiffs don't allege any of these statutory rebuttals. The pertinent question is solely whether the design-defect, negligence, and breach-of-warranty claims brought by Plaintiffs are in substance failure-to-warn claims. This statutory framework being relatively new, it appears that neither the Texas Supreme Court

nor the Fifth Circuit have addressed this precise issue. But district courts have each applied the same general framework. For example, see *Parachim v Biogen Inc*, 2019 WL 9654875, *2–3 (WD Tex); *Gonzalez v Bayer Healthcare Pharmaceuticals*, 930 F Supp 2d 808, 819–21 (SD Tex 2013); *Del Valle v Qualitest Pharmaceuticals Inc*, 2012 WL 2899406, *3 (SD Tex), affd sub nom *Lashley v Pfizer, Inc*, 750 F3d 470 (5th Cir 2014, *per curiam*); *Eckhardt v Qualitest Pharmaceuticals Inc*, 889 F Supp 2d 901, 907 (SD Tex 2012), affd 751 F3d 674 (5th Cir 2014).

The initial inquiry is whether each asserted claim falls within the definition of *products liability action*. See Tex Civ Prac & Rem Code § 82.001(2); see also *Sanchez v Liggett & Myers, Inc*, 187 F3d 486, 489–91 (5th Cir 1999). For any claim that does, the further inquiry is whether the claim in substance alleges that the injury was caused by a failure to warn. This requires scrutiny of the complaint and determination whether the allegations actually describe a failure-to-warn claim, despite characterizations and labels stated by the plaintiff. See Tex Civ Prac & Rem Code § 82.007(a); see also *Parachim*, 2019 WL 9654875 at *2–3; *Gonzalez*, 930 F Supp 2d at 819–21. Any claim that in substance alleges injury caused by failure to warn is subject to the statutory presumption and thus barred by the Texas Civil Practice and Remedies Code.

a. Encompassment within *products liability action*

Texas Civil Practice and Remedy Code § 82.001(2) defines *products liability action* to mean "any action against a manufacturer or seller for recovery of damages arising out of personal injury, death, or property damage allegedly caused by a defective product whether the action is based in strict tort liability, strict products liability, negligence, misrepresentation, breach of express or implied warranty, or any other theory or combination of theories." Texas courts are clear that this definition is to be applied broadly. For example, see *Fresh Coat, Inc v K-2, Inc*, 318 SW3d 893, 900 (Tex 2010); *Iacono v Stanley Black & Decker, Inc*, 2016 WL 2745401, *4 (Tex App—Houston [1st Dist] no pet).

Plaintiffs allege that Pauline Moncibaiz sustained a personal injury from the use of a defective product and that such injury gives rise to claims for strict liability, negligence, and breach of

warranty. Under Texas law, those claims are *products liability actions*. Plaintiffs don't dispute this. See Dkt 18 at 11–12.

b. Characterization as failure-to-warn claims

The original pleading of this action specifically referenced a failure-to-warn theory. Plaintiffs amended their claims to address the prior motion to dismiss in this regard. The question is whether the claims as amended continue in substance to be ones for failure to warn.

The complaint by its nature includes failure-to-warn references. *First,* it says that Plaintiffs lacked important information about Prempro. That is, it lists three studies that purportedly highlight the risks involved in using Prempro, with allegation that Pauline Moncibaiz "was unaware" of them. Dkt 6 at ¶¶ 11–15. Specifically, the complaint alleges that she "first became aware that the Prempro could have caused her cancer in late 2018." Id at ¶ 15.

Second, the complaint alleges that Defendants should have warned her that the risk of developing cancer could vary with the dose used but failed to do so. Id at ¶ 17.

Third, the complaint says that the warnings approved by the FDA were substantively inadequate:

> Defendants['] warnings and information about Prempro were inadequate because Defendants failed to inform Plaintiff's physician that bioidentical hormones did not have a risk of breast cancer and were a safer alternative to conjugated hormones like Prempro, represented there was no difference with the risk of breast cancer at different doses, and failed to inform Plaintiff's physician that there was a lower risk of breast cancer at lower doses of conjugated estrogens like Prempro.

Id at ¶ 28.

Plaintiffs incorporate these allegations into each of their legal claims. Id at ¶¶ 26, 35, 39. Defendants thus argue that this language shows that the claims formally pleaded as those for design defect, negligence, and breach of warranty are really just

dressed-up failure-to-warn claims. See Dkt 12 at 16–17. In doing so, they address all three claims together. But the elements of each cause of action are distinct and warrant separate consideration.

i. Design defect

To plead a products-liability claim for design defect under Texas law requires the plaintiff to allege that:

- *First,* the product was defectively designed so as to render it unreasonably dangerous;
- *Second,* a safer alternative design existed; and
- *Third,* the defect was a producing cause of the injury for which the plaintiff seeks recovery.

Goodner v Hyundai Motor Co, 650 F3d 1034, 1040 (5th Cir 2011), quoting *Timpte Industries, Inc v Gish*, 286 SW3d 306, 311 (Tex 2009).

Plaintiffs' complaint structurally seeks to follow those elements:

> 28. *Defendants['] warnings and information about Prempro were inadequate* because Defendants *failed to inform Plaintiff's physician* that bioidentical hormones did not have a risk of breast cancer and were a safer alternative to conjugated hormones like Prempro, represented there was no difference with the risk of breast cancer at different doses, and *failed to inform Plaintiff's physician* that there was a lower risk of breast cancer at lower doses of conjugated estrogens like Prempro.
>
> 29. The Prempro Plaintiff took was defectively designed because:
>
> > (a) it was made from horse urine and contained hormones that are not natural hormones in human women, and increased the risk of breast cancer, rather than containing only hormones found in human woman such as bioidentical hormones that do not increase the risk of breast cancer;

> (b) it was in a dose that causes breast cancer.
>
> 30. The above design defects were each a producing cause of Plaintiffs injuries and damages.
>
> 31. One or more of the following safer alternative designs for the product existed that would have prevented or significantly reduced the risk of Plaintiff's injury without substantially impairing the product's utility, and that was economically and technologically feasible at the time the product left Defendant's control by the application of existing or reasonably achievable scientific knowledge:
>
> (a) bioidentical hormones;
>
> (b) a lower dose conjugated hormone.
>
> 32. The above design defect or defects rendered the product unreasonably dangerous as designed considering the utility of the product and the risks involved in its use.
>
> 33. The Prempro Plaintiff took was unreasonably dangerous for the reasons more particularly set forth above.

Dkt 6 at ¶¶ 28–33 (emphasis added).

As emphasized above, a reference to deficient warnings recurs in the amended complaint. The pertinent question is whether these allegations actually describe an injury caused by a failure to warn, when scrutinized against the totality of Plaintiffs' complaint and despite the labels and characterizations they give to their claims. See Tex Civ Prac & Rem Code § 82.007(a). They do, for two reasons.

The first is the asserted causal connection between the use of Prempro and the allegation of resulting injury. Plaintiffs assert that Prempro is unreasonably dangerous as designed, and that Pauline Moncibaiz's physician should have been informed of the risks involved in using Prempro and of potentially safer alternatives. But that latter assertion invokes the *learned*

intermediary doctrine as applied under Texas law. For example, see *Murthy v Abbott Laboratories*, 847 F Supp 2d 958, 967 (SD Tex 2012), citing *Ackermann v Wyeth Pharmaceuticals*, 526 F3d 203, 207 (5th Cir 2008). As a general rule, the doctrine provides that a manufacturer fulfills its duty to warn where it provides adequate warnings to a credible intermediary. See *Alm v Aluminum Co of America*, 717 SW2d 588, 591–92 (Tex 1986) (citations omitted). The intermediary is then presumed to pass along the warnings to germane clients. See *Porterfield v Ethicon, Inc*, 183 F3d 464, 467–68 (5th Cir 1999), citing *Alm*, 717 SW2d at 591–92. A drug manufacturer "remains liable for injuries sustained by the ultimate user" where it provides inadequate warnings to the physician. *Murthy*, 847 F Supp 2d at 968, quoting *Porterfield*, 183 F3d at 467–68.

With this doctrine in mind, any allegation by Plaintiffs that Defendants failed to adequately inform the prescribing physician of pertinent risks reduces to allegation that Defendants failed to adequately inform *Pauline Moncibaiz* of those risks. But the FDA-approved warnings were provided to the physician. And regardless, the necessary implication is that Pauline Moncibaiz would have opted to use an alternative to Prempro had she been properly warned. As such, the cause of injury is more appropriately linked to the allegation of alleged inadequate warnings—not to an allegedly underlying design defect. It follows, then, that the core of Plaintiffs' complaint is based on an alleged failure to warn by Defendants. Other courts in this district have reached the same conclusion when considering similar pleadings. For example, see *Gonzalez*, 930 F Supp 2d at 819 (as to prescription drug Mirena); *Del Valle*, 2012 WL 2899406 at *3 (as to prescription drug Reglan); *Eckhardt*, 889 F Supp 2d at 907 (also as to Reglan).

A second and independent reason relates to what it means for a product to be considered *defective* and *unreasonably dangerous* under Texas law. A plaintiff must show both of those things to plead a design-defect claim. *Timpte Industries*, 286 SW3d at 311. And in relation to these concepts, Texas law incorporates comment k to § 402A of the Restatement (Second) of Torts. See *McKisson v Sales Affiliates*, 416 SW2d 787 (Tex 1967) (adopting

comment k); see also *Reyes v Wyeth Laboratories*, 498 F2d 1264, 1271–74 (5th Cir 1974) (recognizing same). Texas expressly applies comment k in the prescription-drug context. *In re DuPuy Orthopedics, Inc, Pinnacle Hip Implant Product Liability Litigation*, 888 F3d 753, 772 (5th Cir 2018), citing *Centocor, Inc v Hamilton*, 372 SW3d 140, 165 (Tex 2012).

Comment k provides that some products, when "properly prepared, and accompanied by proper directions and warning," are as a matter of law neither defective nor unreasonably dangerous. Restatement (Second) of Torts § 402A comment k (ALI 1965). This recognizes that some products "are quite incapable of being made safe for their intended and ordinary use." Ibid. But it's deemed acceptable that their use will involve an "unavoidable high degree of risk" because that risk is a necessary condition of providing beneficial products. Ibid. Comment k notes that this is true in particular for many "drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician." Ibid.

This means that prescription drugs are neither defective nor unreasonably dangerous as a matter of Texas law *so long as* they are marketed according to their purpose and accompanied by proper instructions and warnings. The Texas Supreme Court and the Fifth Circuit don't appear to have determined whether the presumption against liability under Texas Civil Practice and Remedies Code § 82.007(a) applies to the design-defect analysis as governed by comment k. But most courts that have considered the question hold that it does. For example, see *McKay v Novartis Pharmaceutical Corp*, 934 F Supp 2d 898, 909–11 (WD Tex 2013); *Holland v Hoffman-La Roche, Inc*, 2007 WL 4042757, *3 (ND Tex); but see *Lea v Wyeth LLC*, 2011 WL 13192701, *11–14 (ED Tex). Courts outside of the Fifth Circuit applying Texas law have also reached the same conclusion. For example, see *Solomon v Bristol Myers Squibb Co*, 916 F Supp 2d 556, 571–72 (DNJ 2013); *In re Accutane Products Liability*, 2013 WL 7848637, *3 (MD Fla).

This Court agrees that the presumption against liability applies to the design-defect analysis under comment k, which recognizes that some products (like prescription drugs) simply

can't be produced to eliminate all risk of serious harm—at least in certain approved uses as to some persons. It is inconsistent to argue that a prescription drug such as Prempro was designed defectively simply because it may cause cancer or pose other health risks. To the contrary, such risks aren't defects but are rather unavoidable byproducts of proper design and manufacture. And under comment k, Defendants' only duty in this regard is to manufacture Prempro according to the approved process and to supply it with the approved directions and warnings.

Plaintiffs don't assert that the Prempro taken by Pauline Moncibaiz was manufactured at variance from the federally approved process. This means that the only other way to plead a design-defect claim is to argue Prempro's warnings were inadequate. And to do that necessarily means Plaintiffs' claim is one for an injury "caused by a failure to provide adequate warnings or information with regard to a pharmaceutical product." Tex Civ Prac & Rem Code § 82.007(a); see also *McKay*, 934 F Supp 2d at 909–11; *Holland*, 2007 WL 4042757 at *3.

The claim asserted by Plaintiff for design defect is in substance one for failure to warn. The presumption against liability applies, which Plaintiffs don't attempt to rebut. As such, the design-defect claim must be dismissed.

ii. Negligence

A manufacturer owes a duty to its customers under Texas law to design a product such that its use doesn't involve an unreasonable risk of harm. See *Gonzales v Caterpillar Tractor Co*, 571 SW2d 867, 871–72 (Tex 1978), quoting Restatement (Second) of Torts § 395 (ALI 1965). With that particular duty in mind, the elements of a negligent-design claim are otherwise the same as that of a traditional negligence claim—duty, breach, causation, and damages. For example, see *Zakaria v STL International, Inc*, 2020 WL 4368096, *5 (SD Tex), citing *Syrie v Knoll International*, 748 F2d 304, 309 (5th Cir 1984) and *Gonzales*, 571 SW2d at 871.

Neither the Texas Supreme Court nor the Fifth Circuit appears to have addressed a prescription-drug case where negligence claims were argued in light of the new statutory

framework to be in substance failure-to-warn claims. But application of fundamental tort-law principles shows that Plaintiffs' negligent-design claim is based on failure to warn. This is because a manufacturer can't be liable for negligent design where the product at issue has been shown to not be unreasonably dangerous under a design-defect analysis. See *Simien v CR Bard, Inc*, 2020 WL 4922331, *9 (ED Tex), citing *Garrett v Hamilton Standard Controls, Inc*, 850 F2d 253, 257 (5th Cir 1988). True, such actions are distinct insofar as strict liability "looks at the product itself and determines if it is defective," while negligence "looks at the acts of the manufacturer and determines if it exercised ordinary care in design and production." *Gonzales*, 571 SW2d at 871; see also *McClennan v American Eurocopter Corp*, 245 F3d 403, 431 (5th Cir 2001), citing *Syrie*, 748 F2d at 307, 309. But the Fifth Circuit in *Garrett* explained at length that defeat of the design-defect claim can also dispose of a related negligence claim:

> Thus, although a negligence claim requires a different showing from a strict liability claim, a manufacturer logically cannot be held liable for failing to exercise ordinary care when producing a product that is not defective because: (1) if a product is not unreasonably dangerous because of the way it was manufactured, it was not negligent to manufacture it that way and (2) even if the manufacturer was somehow negligent in the design or production of the product, that negligence cannot have caused the plaintiff's injury because the negligence did not render the product "unreasonably dangerous."

850 F2d at 257 (citations omitted).

As shown above, Texas law provides that prescription drugs aren't unreasonably dangerous provided that they are properly prepared and include adequate directions and warnings. *In re DuPuy Orthopedics*, 888 F3d at 766, citing Restatement (Second) of Torts § 402A comment k. Plaintiffs don't allege that the Prempro at issue here was improperly prepared. And so their only avenue to prove unreasonable danger is to prove inadequate warnings. It

follows, then, that Plaintiffs' negligence claim is really one for failure to warn. The presumption against liability again applies, which Plaintiffs don't attempt to rebut.

Beyond this, and as with the design-defect claim, the *learned intermediary doctrine* also pertains. The Texas Supreme Court holds that the doctrine applies to all claims where the "crux" of the asserted claim is the "alleged failure to provide an adequate warning." *Centocor*, 372 SW3d at 169. This being so, Defendants have discharged any pertinent duty under a negligence theory by providing Prempro with adequate warnings.

The negligence claim must be dismissed. Courts in this district have concluded the same when faced with similar claims and arguments. For example, see *Murthy*, 847 F Supp 2d at 977; *Del Valle*, 2012 WL 2899406 at *2.

iii. Breach of implied warranty

To state a claim for breach of the implied warranty of merchantability, a plaintiff must plead that the defendant sold or leased a product to the plaintiff, the product was unmerchantable, the plaintiff notified the defendant of the breach, and the plaintiff suffered injury. For example, see *Woohouse v Sanofi-Aventis US LLC*, 2011 WL 3666595, *4 (WD Tex), quoting *Polaris Industries, Inc v McDonald*, 119 SW3d 331, 336 (Tex App—Tyler 2003, no pet), in turn citing Tex Bus & Commerce Code §§ 2.314, 2.607(c)(1), 2.714, 2.715. A product is *merchantable* if, among other characteristics, it is "fit for the ordinary purposes for which such goods are used." Tex Bus & Commerce Code § 2.314(b)(3).

This claim fails for much the same reason as the negligence claim. In breach-of-warranty parlance, Plaintiffs must prove that Prempro is unmerchantable—that is, that it's not fit for the ordinary purpose of treating menopause symptoms and preventing osteoporosis in menopausal women. As with negligence, this claim is linked to the design-defect claim. This is so because a product "cannot be unfit for ordinary use but not unreasonably dangerous, nor can it be unreasonably dangerous but fit for ordinary use; it must be both or neither." *Smith v Chrysler Group, LLC*, 909 F3d 744, 752 (5th Cir 2018), quoting *Hyundai Motor Co v Rodriguez*, 995 SW2d 661, 665 (Tex 1999) and citing *Otis Spunkmeyer, Inc v Blakley*, 30 SW3d 678, 684 (Tex App—

Dallas 2000, no pet). And so, Plaintiffs can't support their breach-of-warranty claim if Prempro isn't unreasonably dangerous. And they can't prove that Prempro isn't unreasonably dangerous without arguing that its warnings are inadequate.

It follows that the breach-of-warranty claim is in substance a failure-to-warn claim. The presumption against liability again applies, which Plaintiffs don't attempt to rebut. It also means that the *learned intermediary doctrine* applies. As such, the failure-to-warn claim must be dismissed. Other decisions confirm this result. See *Murthy*, 847 F Supp 2d at 977; *Del Valle*, 2012 WL 2899406 at *2.

c. Failure to state a claim

Defendants also argue that even if Plaintiffs' claims aren't in substance based on a failure to warn, they still fail to state a claim under Rule 12(b)(6). Dkt 12 at 21–23. This argument needn't be addressed in light of the above determination.

4. Opportunity to replead

A district court "should freely give leave [to amend] when justice so requires." FRCP 15(a)(2). The Fifth Circuit has long held that this evinces a bias in favor of granting leave to amend. See *Dussouy v Gulf Coast Investment Corp*, 660 F2d 594, 597(5th Cir 1981); *Carroll v Fort James Corp*, 470 F3d 1171, 1175 (5th Cir 2006). But whether to grant leave to amend is within the sound discretion of the district court. *Pervasive Software Inc v Lexware GmbH & Co KG*, 688 F3d 214, 232 (5th Cir 2012), quoting *Wimm v Jack Eckerd Corp*, 3 F3d 137, 139 (5th Cir 1993). It may be denied "when it would cause undue delay, be the result of bad faith, represent the repeated failure to cure previous amendments, create undue prejudice, or be futile." *Morgan v Chapman*, 969 F3d 238, 248 (5th Cir 2020), citing *Smith v EMC Corp*, 393 F3d 590, 595 (5th Cir 2004).

Plaintiffs sought and obtained leave to replead their claims when faced with a prior motion to dismiss raising the same legal challenges to their original complaint. Even though it is now determined that the amended complaint fails to plead around a failure-to-warn claim, this is the first ruling received by Plaintiffs as to their remaining claims. These are complicated legal issues, making it quite tenuous to conclude at this juncture that further amendment would necessarily be futile. The *free leave* accorded by

Rule 15(a)(2) suggests that Plaintiffs be allowed one further attempt to plead their claims, subject to the dictates of Rule 11(b).

Plaintiffs' claims will be dismissed without prejudice.

5. Conclusion

The motion by Defendants Pfizer, Inc, Wyeth Holdings, LLC, and Wyeth LLC to dismiss the claims asserted by Plaintiffs Pauline and Rick Moncibaiz is GRANTED. Dkt 12.

The claims are DISMISSED WITHOUT PREJUDICE.

Plaintiffs may seek leave to amend by April 23, 2021.

SO ORDERED.

Signed on March 31, 2021, at Houston, Texas.

Hon. Charles Eskridge
United States District Judge